Charles M. Lizza William C. Baton Sarah A. Sullivan SAUL EWING LLP One Riverfront Plaza, Suite 1520 Newark, NJ 07102-5426 (973) 286-6700

Attorneys for Plaintiffs
Sumitomo Dainippon Pharma Co., Ltd.
and Sunovion Pharmaceuticals Inc.

#### **OF COUNSEL:**

Joseph M. O'Malley, Jr. Preston K. Ratliff II Bruce M. Wexler PAUL HASTINGS LLP 200 Park Avenue New York, NY 10166 (212) 318-6000

## UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

SUMITOMO DAINIPPON PHARMA CO., LTD. and SUNOVION PHARMACEUTICALS INC.,

Plaintiffs,

v.

EMCURE PHARMACEUTICALS LIMITED, *et al.*,

Defendants.

Civil Action No. 15-280 (SRC) (CLW) Civil Action No. 15-281 (SRC) (CLW) Civil Action No. 15-6401 (SRC) (CLW) (Consolidated)

(Filed Electronically)

RESPONDING BRIEF IN SUPPORT OF SUNOVION'S CLAIM CONSTRUCTION

### TABLE OF CONTENTS

	ŀ	'age	
INTRODUC	CTION	1	
ARGUMEN	NT	3	
A.	Defendants' Construction Conflicts With The Intrinsic Evidence	4	
B.	Defendants Favor Extrinsic Evidence Over The Intrinsic Record	10	
C.	Defendants' Claim-Limiting Arguments Have Been Rejected By The Federal Circuit	12	
D.	Defendants And Their Expert Have Failed To Propose A Construction For The Disputed Claim Term, "Or An Acid Additional Salt Thereof"	16	
CONCLUSION			

### TABLE OF AUTHORITIES

Cases	Page(s)
Adams Respiratory Therapeutics, Inc. v. Perrigo, 616 F.3d 1283 (Fed. Cir. 2010)	5
Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp., Civil Action No. 97-4203, 2000 WL 34204509 (N.D. Cal. Feb. 28, 2000)	8
Eli Lilly & Co. v. Zenith Goldline Pharms., LLC, Civil Action No. 01-0443, 2001 WL 1397304 (S.D. Ind. Oct. 29, 2001)	14
Howmedica Osteonics Corp. v. Depuy Orthopaedics, Inc., Civil Action No. 11-6498, 2013 WL 3455727 (D.N.J. July 9, 2013)	8
<i>i4i v. Microsoft</i> , 598 F.3d 831 (Fed. Cir. 2010)	6-7
Pfizer, Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284 (Fed. Cir. 2006)	passim
Pfizer Inc. v. Teva Pharms. USA, Inc., 555 F. App'x 961 (Fed. Cir. 2014)	2, 13, 14
Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005)	12

#### **INTRODUCTION**

Defendants' opening brief gives lip service to well-established claim construction principles, but disregards them in favor of a claim construction crafted solely to avoid infringement. For example, Defendants state that the patent specification "is the single best guide to the meaning of a disputed term," but they do not mention the '372 patent's explicit teaching that its chemical compounds "can have stereo and optical isomers, and *this invention involves these isomers or their mixtures as well.*" Nor do Defendants address, or even acknowledge, that after studying Claim 14 and the '372 patent specification, each of the defendants *admitted* that Claim 14 encompasses the chemical compound lurasidone, as Sunovion proposes with its claim construction.<sup>2</sup>

Defendants do not base their proposed construction on how a person of ordinary skill would understand Claim 14 in the context of the patent specification. Instead, Defendants' flawed analysis is based on two book excerpts published many years after the '372 patent application filing and five journal articles having nothing to do with the '372 patent or its class of compounds. As a result, it is no surprise that Defendants' proposed construction conflicts with the intrinsic record and would impermissibly exclude important preferred embodiments. Moreover, Defendants

<sup>&</sup>lt;sup>1</sup> (D.I. 91, Defendants' Opening Claim Construction Brief at 9; Exh. 1, at 4:51-53 (emphasis added).) "Exh. \_\_" refers to the exhibits attached to the June 15, 2016 or August 16, 2016 Declarations of Preston K. Ratliff II submitted in support of Sunovion's claim construction.

<sup>&</sup>lt;sup>2</sup> D.I. 90, Sunovion's Opening Claim Construction Brief at 1-2, 11.

devote many pages of their opening brief to describing and highlighting an exemplary claimed compound (Compound No. 101).<sup>3</sup> Defendants' focus on this compound is misleading because, as their expert conceded at deposition, the chemical structure depicted in Claim 14 is *not* identical to Compound No. 101.<sup>4</sup> Notably absent from Defendants' brief and their expert Dr. Steven W. Baldwin's declaration is any statement from the intrinsic record calling for disavowal of claim scope that would limit Claim 14 to a specific 50:50 mixture of two chemical compounds. This is because there are no such statements.

Further, as explained in detail below, Defendants and Dr. Baldwin offer this

Court the very same misguided and illogical reasoning that Defendant Teva and
another generic drug manufacturer argued before two Federal Circuit panels and two
district court judges when they tried unsuccessfully to redefine the innovators'
chemical compound patents.<sup>5</sup>

Sunovion, on the other hand, offers a construction that derives from the plain language of Claim 14 and is consistent with the patent specification, file history, and understanding of a person of ordinary skill. To accept Sunovion's construction, the

<sup>&</sup>lt;sup>3</sup> D.I. 91, at 11-21.

<sup>&</sup>lt;sup>4</sup> Exh. 10, 51:15-53:6, 58:3-6.

<sup>&</sup>lt;sup>5</sup> Pfizer, Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284, 1290 (Fed. Cir. 2006); Pfizer Inc. v. Teva Pharms. USA, Inc., 555 F. App'x 961, 965-66 (Fed. Cir. 2014).

Court does not need to rely on any extrinsic evidence, read in any extraneous limitation, or otherwise disregard well-established claim construction principles.<sup>6</sup>

#### **ARGUMENT**

Claim Term	Sunovion's Construction	Defendants' Construction
"The imide compound of the formula:	plain meaning — refers to lurasidone, lurasidone's enantiomer, as well as mixtures thereof	A racemic mixture of two enantiomers of which the structural formula is representative
"or an acid addition salt thereof"	plain meaning — includes, for example, lurasidone hydrochloride	Defendants disagree that this term encompasses lurasidone hydrochloride and refuse to provide a construction

The parties dispute whether Claim 14 encompasses lurasidone, as Sunovion proposes and Defendants *admitted* in their Paragraph IV Notice Letters, or whether Claim 14 excludes lurasidone and is narrowly limited to a racemic mixture, as Defendants now argue. The parties also dispute whether the term "or an acid addition salt thereof" refers to, for example, the particular form of lurasidone within

<sup>&</sup>lt;sup>6</sup> Defendants incorrectly state (1) that "[t]he parties agree ... that while the structural formula in Claim 14 depicts a single enantiomer, the structural formula must encompass a racemic mixture of the depicted enantiomer and its mirror image" and (2) Sunovion has acknowledged "that the formula of Claim 14 is directed only to the particular enantiomer depicted by the formula . . . ." (D.I. 91, at 8-9 and n.4.) Sunovion maintains that the drawing depicted in Claim 14 is directed to lurasidone, lurasidone's enantiomer, as well as mixtures thereof.

Defendants' proposed generic products (lurasidone hydrochloride), as Sunovion proposes. Despite the parties' disagreement as to the plain and ordinary meaning of this claim term, Defendants and their expert do not offer any construction for this term. (D.I. 81, Joint Claim Construction and Prehearing Statement at 4; Exh. 10, 238:3-7, 240:15-20.)

#### A. Defendants' Construction Conflicts With The Intrinsic Evidence

Despite claiming so, Defendants' construction is not consistent with the intrinsic evidence. Citing *Phillips*, Defendants admit that the patent specification "necessarily informs the proper construction of the claims." (D.I. 91, at 10.)

Defendants also admit that the patent specification is of "paramount importance."

(D.I. 91, at 9.) Yet, neither Defendants nor their expert Dr. Baldwin mention the '372 patent's teaching that its chemical compounds "can have stereo and optical isomers, and *this invention involves these isomers or their mixtures as well.*" (Exh. 1, 4:51-53 (emphasis added).) It cannot be disputed that this teaching is one of the clearest statements in the intrinsic record that speaks to the '372 patent inventors' intent to claim individual enantiomers (*e.g.*, lurasidone and lurasidone's enantiomer) as well as mixtures of the enantiomers.

<sup>&</sup>lt;sup>7</sup> Sunovion cited this teaching of the '372 patent as supporting its construction in the Joint Claim Construction Statement. (D.I. 81, at 14.)

Defendants and Dr. Baldwin also do not acknowledge the '372 patent's important teaching that Example 1 of the patent is a "preferred embodiment." (Exh. 1, 14:56-60.)<sup>8</sup> As explained in Sunovion's opening brief, Example 1 consists of five subparts that disclose, among other things, the chemical compound lurasidone hydrochloride (Compound No. 105), lurasidone's enantiomer in a hydrochloride salt form (Compound No. 104), and a mixture of this enantiomeric pair in a hydrochloride salt form (Compound No. 101). (D.I. 90, at 12.)<sup>9</sup>

Based on Defendants' selective recitation of the intrinsic evidence, Defendants' proposed construction would include a preferred embodiment (Compound No. 101), while improperly excluding others (lurasidone hydrochloride and its enantiomer) that are explicitly taught in the same Example. *Adams Respiratory Therapeutics, Inc. v. Perrigo*, 616 F.3d 1283, 1290 (Fed. Cir. 2010) ("A claim construction that excludes the preferred embodiment is rarely, if ever, correct and would require highly persuasive evidentiary support." (internal quotation marks omitted)). <sup>10</sup>

<sup>-</sup>

<sup>&</sup>lt;sup>8</sup> Supra note 7.

<sup>&</sup>lt;sup>9</sup> At deposition, Dr. Baldwin conceded that these compounds were preferred embodiments. (Exh. 10, 223:4-24.)

Defendants ignore what is plainly taught in the '372 patent specification and, similar to the defendants in *Ranbaxy*, they pass over the total absence of any reference to a "racemic" mixture in the '372 patent. *Pfizer v. Ranbaxy*, 457 F.3d at 1289 ("There is no further disavowal of claim scope that would limit the '893 patent to trans-racemates. Indeed, as noted by the district court, the terms 'racemate' or 'racemic mixture' do not appear in the '893 patent . . . .")

Defendants also argue that a patent's file history "provides further evidence of a claim's scope." (D.I. 91, at 10.) For example, quoting *Phillips*, Defendants state that "the prosecution history provides evidence of how the PTO and the inventor understood the patent." (Id.) Defendants and Dr. Baldwin, however, ignore that the USPTO understood Claim 14 to encompass lurasidone. Specifically, Sunovion identified Claim 14 of the '372 patent to the USPTO as covering the active ingredient lurasidone hydrochloride in support of an application for a patent term extension ("PTE"). (D.I. 90, at 7.) After reviewing Sunovion's application, the USPTO granted a term extension pursuant to 35 U.S.C. § 156. (*Id.*) During his deposition, Dr. Baldwin confirmed that he knew that Sunovion's PTE application and the USPTO's response were part of the file history, and that he was aware of this intrinsic evidence before submitting his declaration. (Exh. 10, 83:4-84:7, 84:17-85:2.) Dr. Baldwin's declaration conveniently fails to comment on this intrinsic evidence that conflicts with his claim construction opinion. (Exh. 10, 91:14-20.)

Defendants' only citations to the '372 patent file history are to certain papers concerning restriction requirements, the August 30, 1994 USPTO Office Action, the applicants' responses thereto, and papers showing when Claim 14 was first added to the application. (D.I. 91, at 11-13, 19-20.) Taken as a whole, those portions of the file history show that in addition to lurasidone and lurasidone's enantiomer, Compound No. 101 is one of the compounds that the inventors intended to claim. *i4i v. Microsoft*, 598 F.3d 831, 843 (Fed. Cir. 2010) (refusing to limit a claim based on

statements that were "pluck[ed] from the prosecution history" and do not "clearly and unmistakably disavow" claim scope).

The quotations that Defendants selected from the file history, when considered in context of the intrinsic evidence as a whole, support Sunovion's construction as illustrated below:

- "In particular, it is applicants' desire to *elect a group which encompasses Compound No. 101, namely Example 1* in the application."
- "the applicants provisionally elect the species of Compound No. 101, *namely Example 1*."

(D.I. 91, at 13 (citing March 30, 1995 Response) (emphasis added).) As shown above, the first quotation plainly demonstrates that the inventors claimed more than a single compound: "a group which encompasses Compound No. 101, namely Example 1." (D.I. 91, at 13 (emphasis added).) Example 1 exemplifies not only Compound No. 101, but other claimed compounds. For example, lurasidone hydrochloride (Compound No. 105) is described in Example 1 as the (-)-isomer of Compound No. 101 in the form of a hydrochloride salt. (Exh. 1, 32:17-23.) Example 1 also describes a different salt form of lurasidone as the (-)-isomer of Compound No. 101 in the form of D-tartrate (Compound No. 103). (Exh. 1, 31:24-55.) Further, Example 1 describes lurasidone hydrochloride's enantiomer as the (+)-isomer of Compound No. 101 in the form of a hydrochloride salt (Compound No. 104) as well as a different salt form of lurasidone's enantiomer as the (+)-isomer of Compound No.

101 in the form of an L-tartrate salt (Compound No. 102). (Exh 1, 31:11-23, 32:1-14.)

The portions of the file history relied on by Defendants concerning restriction requirements do not call for disavowal of claim scope that would limit Claim 14 to a specific 50:50 mixture of two chemical compounds, nor could they. As Judge Wigenton of this Court has explained, restriction requirements are simply administrative tools that "do not help inform courts with respect to claim construction." *Howmedica Osteonics Corp. v. Depuy Orthopaedics, Inc.*, Civil Action No. 11-6498, 2013 WL 3455727, at \*25 (D.N.J. July 9, 2013). This is because restriction is a routine procedure used by patent examiners to reduce burdens that may arise in applications having more than one patentably distinct invention. *See Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp.*, Civil Action No. 97-4203, 2000 WL 34204509, at \*15 (N.D. Cal. Feb. 28, 2000) ("A restriction requirement is not a rejection and it cannot be used to controvert the plain language of the claim."). <sup>11</sup>

Importantly, Defendants do not address, or even acknowledge, that after studying Claim 14, the '372 patent specification, and the '372 patent file history, each of the Defendants *admitted* that Claim 14 encompasses the chemical compound lurasidone. (D.I. 90, at 2, fn. 3-5.) Defendants were on notice prior to the filing of

<sup>&</sup>lt;sup>11</sup> Even a cursory review of the '372 patent demonstrates that any restriction requirement issued during patent prosecution did not limit the patent claims to a single compound, as Defendants argue. Claims 1-20 are directed to many different compounds. (Exh. 1, 60:35-65:50.)

their opening brief that their pre-litigation admissions were contrary to the construction that they advance now. (D.I. 81, at 3.) Moreover, Defendants tried to conceal their pre-litigation admissions from their expert Dr. Baldwin. As confirmed by Dr. Baldwin during his deposition, he saw the reference to Defendants' admissions in Sunovion's opening claim construction brief, but Defendants told him those were documents he did not need to read:

Q. And after seeing that, did you review documents that plaintiffs were citing to concerning plaintiffs' assertion that defendants have already conceded that Claim 14 covers lurasidone?

#### A. I reviewed no other documents, no.

Q. You weren't curious to see what was the basis for plaintiffs' statements in that regard?

## A. I mean I did ask is this a document I should be reading and they said you don't need to.

(Exh. 10, 135:13-136:23) (emphasis added.) After reviewing Defendants Teva's and Emcure's Paragraph IV Notice Letters that provoked the filing of this action, Dr. Baldwin confirmed during his deposition that Teva and Emcure had stated that lurasidone was covered by Claim 14. (Exh. 10, 133:21-134:3, 136:24-137:6, 139:10-141:8, 143:8-18-146:17.)

#### B. Defendants Favor Extrinsic Evidence Over The Intrinsic Record

Instead of acknowledging the '372 patent's teachings that the invention *involves stereo and optical isomers or their mixtures as well*, Defendants ground their claim construction on extrinsic evidence in the form of two book excerpts and five journal articles. Specifically, through their expert Dr. Baldwin, Defendants rely on these extrinsic documents to argue that chemists often draw one enantiomer as shorthand for a racemic mixture. (D.I. 91, at 7; D.I. 91-2, at ¶ 27.)

But the two book excerpts that Dr. Baldwin relies on to make this argument were not even in existence at the time of the invention. As Dr. Baldwin conceded during his deposition, they were not available to the person of ordinary skill because they were not published until many years after July 5, 1991, the date the '372 patent application was submitted to the USPTO. (Exh. 10, 150:7-151:5, 151:16-152:9.) The first extrinsic document, *Organic Chemistry* by Jones, was published in 1997, some six years after the '372 patent application was filed. The second extrinsic document, *Organic Chemistry: Structure and Function* by Vollhardt & Schore, was published nearly 20 years later. This is significant because Dr. Baldwin confirmed that the paragraph he cited in Vollhardt & Schore did not appear in earlier editions of that publication. (Exh. 10, 156:22-157:16.) This also shows the danger of relying on

extrinsic evidence to identify a proper claim construction. <sup>12</sup> Moreover, Dr. Baldwin confirmed at deposition that Vollhardt & Schore concerns "conventions of writing chemical equations," and further confirmed that Claim 14 does not contain a chemical equation. (D.I. 91-2, at ¶ 27; Exh. 10, 158:8-17.)

In addition to the two book excerpts, Dr. Baldwin relies on five journal articles in arguing that a depiction of one enantiomer is often shorthand for a racemic mixture. Sunovion's expert, Professor Stephen G. Davies of the University of Oxford, testified at deposition that he had read these journal articles and that Dr. Baldwin mischaracterized them in his declaration. (Exh. 11, 35:8-14, 41:13-44:8.) For example, Dr. Davies explained that some of those documents use structural drawings to depict single enantiomers and racemic mixtures alike, and the implication by Dr. Baldwin that they only depict racemates is incorrect. (Exh. 11, at 43:11-44:8.)

According to Dr. Davies, a chemical structure is commonly used by a chemist to "depict both single enantiomers, racemates, and any mixture in between, not just racemates." (Exh. 11, at 43:25-44:8.)

<sup>&</sup>lt;sup>12</sup> Defendants' expert, Dr. Baldwin, confirmed during his deposition that extrinsic evidence in general is less reliable than the patent and its prosecution history in determining how to read claim terms. (Exh. 10, 118:22-119:17.)

Although Defendants stress to the Court the "paramount importance of the patent specification and file history," (D.I. 91, at 9), the foundation of their arguments and Dr. Baldwin's opinions, consists primarily of extrinsic sources and the notion that a "standalone structure" is meant to represent a racemic version of that material. <sup>13</sup> As the Federal Circuit noted in *Pfizer v. Ranbaxy*, even if a racemic mixture is commonly represented by depicting one of its constituent enantiomers, it does not follow that the depiction of an enantiomer always represents only a racemic mixture. 457 F.3d at 1290.

### C. Defendants' Claim-Limiting Arguments Have Been Rejected By The Federal Circuit

Defendants offer this Court the same misguided and illogical reasoning that the Federal Circuit rejected in the *Pfizer v. Ranbaxy* and *Pfizer v. Teva* actions. As explained in Section B above, Defendants and Dr. Baldwin try to convince the Court to limit Claim 14 because, in their view, one skilled in the art would represent a racemic mixture by depicting one of its constituent enantiomers. That argument was rejected by the Federal Circuit in *Pfizer v. Ranbaxy*. 457 F.3d at 1289-90.

<sup>&</sup>lt;sup>13</sup> The term "standalone structure" is a term coined by Dr. Baldwin during his deposition, which he used to describe the drawing in Claim 14. (*See* Exh. 10, 47:16-48:7, 50:12-17.) The fact that Dr. Baldwin considers Claim 14 to include a "standalone structure" shows that he is not reading Claim 14 in light of the specification as person of ordinary skill is meant to do in understanding a claim. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*).

In his declaration, Dr. Baldwin argues that the '372 patent discloses many compounds with reaction sequences that produce racemic mixtures. (D.I. 91-2, at ¶ 40.) This claim-limiting argument was also rejected by the Federal Circuit in *Pfizer v. Ranbaxy*. 457 F.3d at 1289-90.

Dr. Baldwin also relies on a 2011 patent application filed by a different group of inventors for a different invention in advocating for a limiting claim construction. (D.I. 91-2, at ¶ 29.) Putting aside the fact that this is yet another extrinsic document that did not exist at the time of the invention, the Federal Circuit held in *Pfizer v*. *Ranbaxy* that statements made during prosecution of a later, unrelated patent cannot be used to interpret claims. 457 F.3d at 1290.

Further, Defendants highlight that the '372 inventors disclosed Compound No. 101 with corresponding test data in tables within the '372 patent and in other places within the intrinsic record. (D.I. 91, at 17-20.) This is no surprise as Compound No. 101 is one of the claimed compounds. As the Federal Circuit explained in *Pfizer v. Teva*, "[a]bsent a clear disavowal or lexicographic definition in the specification or the prosecution history, the reporting of test results limited to a racemate does not warrant importing a racemic limitation" into a claim. *Pfizer v. Teva*, 555 F. App'x at 965. 14

<sup>&</sup>lt;sup>14</sup> The facts of the present action are even more compelling, and confirm that Claim 14 should not be redefined and limited to a racemic mixture. Specifically, the

Defendants' and Dr. Baldwin's flawed analysis is the same reasoning rejected by the Federal Circuit. This is not the first time that a generic drug manufacturer has attempted such an argument. As noted in Sunovion's opening brief, Defendant Teva previously tried to limit a chemical compound claim to a racemic mixture in the hope of avoiding infringement. *Pfizer v. Teva*, 555 F. App'x at 965-66. In addition, Dr. Baldwin has been previously criticized for providing an outcome-driven analysis. *Eli Lilly & Co. v. Zenith Goldline Pharms., LLC*, No. IP 99-38-C H/K, 2001 WL 1397304 (S.D. Ind. Oct. 29, 2001). In *Eli Lilly*, the court devoted an entire section of its opinion, spanning multiple pages, titled, "The Flaws in Dr. Baldwin's Analysis," to deconstruct Dr. Baldwin's flawed obviousness analysis. *Id.* at \*8-11. The court was not persuaded by the opinion offered by Dr. Baldwin that was based on "a methodology that depends on so many arbitrary and artificial constraints to produce the desired result." *Id.* at \*11.<sup>15</sup>

nnof

preferred embodiments of the '372 patent illustrate test data for lurasidone as well as lurasidone's enantiomer and mixtures thereof. (Exh. 1, 12:29-14:55.)

Despite being criticized by the *Eli Lilly* court for conducting an outcome-driven analysis, Dr. Baldwin reverted to this flawed approach in his declaration in the current action, where he arbitrarily, and with hindsight, describes Compound No. 101 as "having three separate molecular regions." (D.I. 91-2, at ¶ 31.) At deposition, Dr. Baldwin revealed the hindsight bias of his declaration when describing lurasidone, by stating that "I mean there isn't a precise number of substructures to this. It depends on how, you know, how much you want to drill down." (Exh. 10, 35:14-36:22.)

Dr. Baldwin's approach to claim construction in this case is similarly outcome-driven. He professes that extrinsic evidence is generally less reliable than intrinsic evidence, but relies primarily on extrinsic evidence to advance his proposed claim construction. And even when Dr. Baldwin reviewed the patent claim at issue in the *Pfizer v. Ranbaxy* action and the key language from the patent specification that the Federal Circuit considered informative of the claim's scope, Dr. Baldwin said that language was irrelevant and concluded that the claim was limited to a racemic mixture. (Exh. 10, 183:6-200:21.) This is the opposite of what the district court and Federal Circuit concluded.<sup>16</sup>

Dr. Baldwin's deposition testimony in this action confirms the outcome-driven nature of his claim construction opinion. Specifically, Dr. Baldwin testified that he reviewed Dr. Davies's declaration and Sunovion's opening claim construction brief, but did not identify a single point that he believed was wrong in either Dr. Davies's analysis or Sunovion's brief. (Exh. 10, 245:8-248:17, 250:8-251:13.) Dr. Baldwin only expressed disagreement with the ultimate conclusion and emphasized the same by stating that he was "not holding anything back." (*Id.*) Conversely, Sunovion's expert explained during his deposition that Dr. Baldwin's analysis was misleading and not helpful in understanding how a person of skill would interpret Claim 14. (Exh.

<sup>&</sup>lt;sup>16</sup> For the Court's convenience, the patent at issue in the *Pfizer v. Ranbaxy* action shown to Dr. Baldwin during his deposition is attached as Exh. 12. Claim 1 of that patent, similar to Claim 14 of the '372 patent, includes a two-dimensional chemical drawing. (Exh. 12, 15:67-17:3.)

11, 35:8-48:14.) Dr. Davies also stated his willingness to further detail why Dr. Baldwin's analysis was flawed for each of the Defendants present at his deposition. (Exh. 11, 48:15-22.) Defendants, perhaps tellingly, chose not to ask Dr. Davies any such questions.

# D. Defendants And Their Expert Have Failed To Propose A Construction For The Disputed Claim Term, "Or An Acid Addition Salt Thereof"

As explained by Sunovion's expert Dr. Davies, the claim term, "or an acid addition salt thereof," should be construed to have its plain and ordinary meaning. (D.I. 90-2, at ¶ 39.) In the case of lurasidone, its hydrochloric acid addition salt is lurasidone hydrochloride. (D.I. 90-2, at ¶ 42.) This is relevant because the active ingredient within each of Defendants' proposed products is lurasidone hydrochloride.

Defendants' expert, Dr. Baldwin, confirmed during his deposition that he has not been asked to consider the claim term, "or an acid addition salt thereof," and has not offered an opinion as to its construction. (Exh. 10, 240:15-20.) Defendants also do not offer any construction for this claim term even though the parties' Joint Claim Construction Statement identifies this term to be in dispute. (D.I. 81, at 21-22.)

It seems Defendants argue against construction of the claim term, "or an acid addition salt thereof," because it exposes the illogical nature of their construction of the first disputed claim term. For example, Defendants argue throughout their opening brief that Claim 14 is directed to a *single* compound: Compound No. 101,

which Defendants describe as a racemic mixture in the form of a hydrochloride salt. (D.I. 90, at 2, 11-12, 23.) Yet, the very language of the claim term, "or an acid addition salt thereof," makes plain that the claim embraces more than just a single compound. (emphasis added.) Defendants' refusal to offer a construction for this claim term appears to be yet another way of avoiding mention of the '372 patent's self-described "preferred embodiments" of Example 1 that include, for example, lurasidone in the form of a hydrochloride (Compound No. 105), lurasidone's enantiomer in the form of a hydrochloride (Compound No. 104), lurasidone's enantiomer in the form of an L-tartrate (Compound No. 102), lurasidone in the form of a D-tartrate (Compound No. 103), as well as the mixtures illustrated in Example 1. (Exh. 1, 30:30-32:22.)

Given that Defendants have deliberately (and perhaps strategically) chosen not to offer a construction for a claim term identified to be in dispute, this Court should accept Sunovion's proposed construction, as it is consistent with the plain and ordinary meaning of that term in light of the intrinsic evidence.

#### **CONCLUSION**

For the foregoing reasons, and the reasons set forth in Sunovion's opening claim construction brief, Sunovion respectfully requests that the Court adopt its construction of the disputed claim terms of the '372 patent.

Dated: August 16, 2016 By: s/William C. Baton

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com

#### Of Counsel:

Joseph M. O'Malley, Jr. Preston K. Ratliff II Bruce M. Wexler PAUL HASTINGS LLP 200 Park Avenue New York, NY 10166 (212) 318-6000

Attorneys for Plaintiffs
Sumitomo Dainippon Pharma Co., Ltd.
and Sunovion Pharmaceuticals Inc.